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780-362—65

In the Supreme Court of the United States

OCTOBER TERM, 1965

No. 187

STEVAN DUROVIC, PETITIONER

v.

ROBERT N. PALMER, R. D. SHERMAN, R. W. CASE, HON. ANTHONY J. CELEBREZZE, BOISFEUILLET JONES, AND JOHN H. GUILL, JR.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The findings and conclusions of the district court (Pet. 17–23) are not reported. The opinion of the court of appeals (Pet. 25–30) is reported at 342 F. 2d 634.

JURISDICTION

The judgment of the court of appeals was entered on March 5, 1965. The petition for a writ of certiorari was filed on May 27, 1965. The jurisdiction of this court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether petitioner's action to enjoin inspection of his drug laboratory by the Food and Drug Administration was properly dismissed on respondents' motion for summary judgment.

STATUTE INVOLVED

Section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355, provides in pertinent part:

> (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.
>
> * * * * *
>
> (i) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. * * *

Section 704 of the Act, 21 U.S.C. 374(a) provides:

> For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics

in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j) or section 507 (d) or (g) of this Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of this Act). * * *

STATEMENT

This action was instituted by petitioner on June 26, 1963, for an injunction ordering the Secretary of Health, Education, and Welfare and the other respondents—who are officials and employees of the Department—to discontinue inspections and investigations under the Federal Food, Drug, and Cosmetic Act, Section 704, 21 U.S.C. 374, with respect to the drug "Krebiozen", and to surrender to petitioner a photograph and negative obtained during an inspection (App. 1–8).[1] The crux of the complaint was that respondents had conducted an inspection of petitioner's manufacturing establishment, Promak Laboratories, in Chicago, Illinois, on a Saturday, June 8, 1963; had photographed a bottle labeled "distilled water" which, petitioner alleged, actually contained his drug in mineral oil solution; and had detained the plaintiff against his will past the usual closing hour (App. 2–6).[2]

Respondents' motion for summary judgment (App. 36–39), which was supported by affidavits (App. 39–

[1] Petitioner also sought copies of investigative reports covering prior inspections and an order prohibiting respondents from uttering statements discrediting petitioner and the drug. These requests were abandoned on appeal (Pet. 30).

[2] The complaint also alleged that respondents had required petitioner's brother, Marko Durovic, to show them an empty establishment owned by him. This allegation is mentioned in petitioner's argument (Pet. 8, 10), but the record shows that the establishment was registered with the Food and Drug Administration, as required by Section 510 of the Act, 21 U.S.C. 360, as a place of manufacture of Krebiozen (App. 110), and that inspection was made there on June 19, 1963, because shipments of frozen horse plasma ostensibly used to prepare Krebiozen had been made to that location (App. 69).

79, 81–87), was granted by the district court (App. 89–95; Pet. 17–23). The court of appeals, which heard the case *en banc,* affirmed (Pet. 25–30). The facts established by the affidavits may be briefly summarized:

Krebiozen is an unorthodox cancer treatment which had been distributed in interstate commerce since 1950.[3] It had not been approved under the new drug provisions of the Act, Section 505, 21 U.S.C. 355, but was distributed only for investigational use under Section 505(i), 21 U.S.C. 355(i), and 21 C.F.R. 130.3.

In February 1963, petitioner was informed by respondent Palmer that an investigation was being undertaken (1) to review the case histories of patients who were allegedly treated successfully with Krebiozen, (2) to determine whether Krebiozen was being lawfully distributed, and (3) to obtain, by inspection, a description of the manufacturing process (App. 49–90). Petitioner objected to phases (2) and (3) of the investigation (App. 50).

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[3] Krebiozen distributed from 1950 to 1959 was claimed to have been produced in Argentina in the late 1940's. Petitioner said that he had brought it into the United States when he entered, and had dissolved it in mineral oil and ampuled it in the early 1950's. Petitioner claimed that he had brought enough powder from Argentina to make 200,000 doses (ampules) (App. 40), but he purchased 1,008,000 empty ampules in 1950 (App. 71, 108). After the Argentina supply was exhausted, two lots were said to have been made from horse blood obtained at the Ken-L Ration plant, in Rockford, Illinois, in 1959 and 1960 (App. 53–55). This production would have yielded enough powder to fill 35,800, 214,800 or 322,200 doses, depending on which of petitioner's statements regarding the yield-per-horse were true (App. 53–54, 71–72).

The compilation of case histories occupied the inspectors' time until May 1, 1963 (App. 51–52). Thereafter, on notice, inspections were made at Promak Laboratories (where Krebiozen was being produced and distributed) but no manufacturing was in progress. The inspectors were only able to observe the equipment and were told by petitioner how he made the drug (App. 54–55).

By May 9, 1963, it was learned that the supply of ampules available for filling orders was low (App. 55). In order to be present when the new supply would be prepared (App. 57–59), the inspectors visited the laboratories on June 5 and 7, 1963, but petitioner was not there (App. 59). Petitioner, who was in Washington, D.C., called the inspectors and told them that he would not return to Chicago until June 11. They informed him that they would be available in case his plans changed (App. 59–60).

On the morning of Saturday, June 8, 1963, the inspectors made a surprise visit to Promak Laboratories, found the establishment open, and presented a written notice of inspection (Pet. 19). Petitioner's secretary was at work, and at least one cash sale was observed while the inspectors were present (App. 60).

Petitioner was engaged in labelling ampules freshly filled with Krebiozen and mineral oil (App. 60). In the presence of the inspectors, petitioner transferred oil which he said contained Krebiozen from a drum to a glass container labeled "distilled water" (App. 30–31, 60–61). The inspectors then photographed the glass container and its label (App. 30, 62).

After considerable discussion regarding the fairness

of the photograph, there ensued a controversy about what would be an adequate sample of Krebiozen for testing by the FDA (App. 25–28, 31–35, 62–67). This lasted until late afternoon because of petitioner's consultation with his attorney and with attorneys in Washington, D.C., and because of the inspectors' consultation with their supervisors. Petitioner ultimately surrendered to the inspectors 100 ampules of Krebiozen and 250 milligrams of Krebiozen mineral oil solution (App. 65–66). This occurred about 6:05 p.m. The inspectors left the laboratory at 6:40 p.m. (App. 67). On July 12, petitioner withdrew Krebiozen from interstate commerce.

ARGUMENT

1. Petitioner claims that the inspection of June 8, 1963, amounted to an unreasonable search and seizure, and that he is entitled to an injunction against future similar inspections and to the suppression of the photograph taken on that occasion. Both courts below held, however, that the inspection about which petitioner complains was a reasonable one under the circumstances. These conclusions, fully supported by the record, need not be reviewed by this Court. *Goldman* v. *United States,* 316 U.S. 129, 135 (1942).

Petitioner's claim that his constitutional rights were infringed because the inspection occurred on a Saturday is groundless. The selection of that day of the week was made necessary by petitioner's action in conducting his manufacturing operations on Saturday after telling the investigators that he would not return to Chicago until the following Monday or Tuesday.

The facts were that the petitioner's establishment was open, that he was engaged in the manufacture of Krebiozen, that his secretary was on the job, and that a cash sale occurred while the inspectors were present (Pet. 19–21). Petitioner, while not controverting these facts, explains them on the basis that a "laboratory is not a commercial establishment" (Pet. 11). But the laboratory clearly qualified as an "establishment in which * * * drugs * * * are manufactured, processed, packed, or held, for introduction into interstate commerce * * *" within the meaning of Section 704 of the Federal Food, Drug, and Cosmetic Act (p. 2, *supra*). Since petitioner was, in fact, manufacturing or processing the drug on Saturday, the inspectors were entitled to enter it for the purpose of viewing the method used.

Petitioner's allegation that he was detained against his will beyond his normal closing hour of 5 p.m. finds no support in any of the affidavits on file, including those offered by petitioner (see App. 12–13, 16, 20, 25–28). The only person who protested, according to the affidavits, was the building custodian, and the inspectors paid him for his overtime (App. 28, 62–67).

Since the inspectors entered petitioner's laboratory at a reasonable time, made reasonable requests for data and samples, and conducted themselves with a view to carrying out their statutory duties (Pet. 22, 29), there was no unreasonable search and seizure. Petitioner was not, therefore, entitled to any of the relief he requested—even assuming *arguendo* that it would have been proper to enjoin further inspections merely because one had been improperly conducted.

2. The district court was correct in entering summary judgment because the affidavits on file showed that there was no genuine issue of fact. Petitioner alleged that respondents had exceeded constitutional limitations in the conduct of their investigations of petitioner and his drug. To meet respondents' affidavits, which demonstrated that the inspectors had acted reasonably, petitioner had to introduce evidence to show that either the time of the inspection or the manner in which it was conducted was unreasonable. Petitioner's affidavits related to whether the photograph might be misleading and stated his opinion regarding the motives of the inspectors in taking the picture and the ultimate use that might be made of it. On no other material question of fact was there any disagreement among the affidavits.[4] Consequently, summary judgment was proper.

Moreover, as the court of appeals concluded (Pet. 29–30), if the disputed photograph is sought to be used unfairly in any civil or criminal proceeding, petitioner will have an adequate remedy at that time. The mere taking of the photograph is no basis for an injunction against future inspection. Nor is the possibility that it may be misleading a ground for ordering its suppression or requiring that it be returned.

[4] Affidavits by petitioner and his brother related to the allegedly defective nature of the more than one million ampules purchased in 1950 (App. 80–81). To the extent that this raised an issue of fact, it did not bear on the reasonableness of the inspection. The mere fact that so many ampules were unaccounted for surely justified the Food and Drug Administration's suspicion, no matter how they were disposed of.

CONCLUSION

It is therefore respectfully submitted that the petition for a writ of certiorari should be denied.

ARCHIBALD COX,
Solicitor General.
FRED M. VINSON, JR.
Assistant Attorney General.
BEATRICE ROSENBERG,
Attorney.

WILLIAM W. GOODRICH,
Assistant General Counsel, Food and Drug Division, Department of Health, Education and Welfare.

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